DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2015

Life Spine, Incorporated
Mr. Randy Lewis
General Manager
13951 South Quality Drive
Huntley, Illinois 60142

Re: K141222
Trade/Device Name: Nautilus Spinal System, Solstice OCT System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP
Dated: January 9, 2015
Received: January 12, 2015

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141222

Device Name
Nautilus Spinal System, Solstice OCT System

Indications for Use *(Describe)*
Nautilus Spinal System:

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The NAUTILUS Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the NAUTILUS Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Solstice OCT System:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3), the SOLSTICE OCT System, when properly used, is intended for: Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; spinal stenosis; fracture/dislocation; Atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery; and tumors.

When used with occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks, rods, and connectors are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Solstice OCT system can also be linked to the Conquest, Pilot, and Nautilus Spinal Systems through the use of transitional rods and rod connectors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Nautilus® Spinal System and the Solstice® OCT System

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510(k) Contact: Randy Lewis
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: February 11th, 2015

Trade Name: Nautilus Spinal System
Solstice OCT System

Regulation Name: 888.3070 Pedicle Screw Spinal System
888.3050 Spinal interlaminal fixation orthosis

Classification: NKB, CFR 888.3070, Class III
MNH, CFR 888.3070, Class II
MNI, CFR 888.3070, Class II
KWP, CFR 888.3050, Class II

Primary Predicate: Sentinel Spinal System (K090343)

Additional Predicates: Theken Atoll OCT Spinal System (K083863)
5.5 Lumbar Cross Connector (K132866)
Globus Revere Addition System (K133350)
Coral Spinal System (K120047)
Conquest Spinal System (K080767)
Nautilus Spinal System (K123373)

Device Description:

The NAUTILUS Thoracolumbar Spinal System consists of an assortment of rods, screws, cross connectors, and axial and offset connectors. The bone screw, head, and taper lock are assembled together during manufacturing to create the NAUTILUS Thoracolumbar Spinal System screw assembly component. The cross, axial, and offset connectors are also assembled during manufacturing. The NAUTILUS Thoracolumbar Spinal System implant components are made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 and cobalt chrome per ASTM 1537. Do

not use any of the NAUTILUS Thoracolumbar Spinal System components with the components from any other system or manufacturer.

The SOLSTICE OCT System is a temporary, titanium alloy (6AL-4V-ELI per ASTM F 136), multiple component system comprised of a variety of non-sterile, single use implantable components. The system consists of an assortment of occipital plates, occipital bone screws, polyaxial screws, hooks, rods, locking caps, connectors and breakaways.

The purpose of this submission is to add transition connectors to both the Nautilus and Solstice Systems.

Indications for Use of the Device:

The Nautilus Spinal System

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The NAUTILUS Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the NAUTILUS Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

The Solstice OCT System

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3), the SOLSTICE OCT System, when properly used, is intended for: Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; spinal stenosis; fracture/dislocation; Atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery; and tumors.

When used with occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Solstice OCT System can be linked to the Nautilus or Conquest Spinal Systems with the use of transitional rods and rod connectors.

Technological Characteristics:
The Nautilus Spinal System and the Solstice OCT System are substantially equivalent to the predicate system in terms of design, materials, indications for use and sizing.

Material:

The NAUTILUS Spinal System is 6AL-4V-ELI titanium manufactured according to ASTM F136 and cobalt chrome per ASTM 1537. The device is comprised of a variety of non-sterile titanium, single use components.

The SOLSTICE OCT System is 6AL-4V-ELI titanium manufactured according to ASTM F136. The device is comprised of a variety of non-sterile titanium, single use components.

Performance Data:
Mechanical testing was included to demonstrate the substantial equivalency of the Nautilus Spinal System and the Solstice OCT System. The testing included static and dynamic compression and static torsion testing per ASTM F1717, static axial and torsional grip per ASTM F1798.

Conclusion:
The information presented demonstrates the substantial equivalency of the Nautilus Spinal System and the Solstice OCT System.